DEC 19 2011

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K102851.

1) Applicant Name and Address

Applicant:	r2 Diagnostics, Inc.
Address:	1801 Commerce Drive
	South Bend, IN 46628
Contact Person:	Marc D. Goldford
Phone #:	574-288-4377
Fax #:	574-288-2272
Email:	marc@r2diagnostics.com
Date of Preparation:	15 November 2010

2) Device Name(s)

Trade Name:	NoFact VIII Deficient Plasma
Classification Name:	Plasma, Factor Deficient (21CFR 864.7290, Product Code GJT)

3) Predicate Device(s)

Stago VIII Deficient Plasma (K892859)

4) Device Description(s)

NoFact VIII Deficient Plasma is a human plasma immunodepleted of Factor VIII and intended for the quantitative determination of Factor VIII activity in citrated plasma from patients suspected of FVIII deficiency. FVIII activity is based on the activated partial thromboplastin time. For in vitro diagnostic use.

5) Intended Use(s)

NoFact VIII Deficient Plasma is a human plasma immunodepleted of Factor VIII and intended for the quantitative determination of Factor VIII activity in citrated plasma from patients suspected of FVIII deficiency. FVIII activity is based on the activated partial thromboplastin time. For in vitro diagnostic use.

6) Technological Characteristic Summary

a. Comparison of the submitted kit and the predicate kit is summarized in the table below:

Comparison of submitted device NoFact VIII Deficient Plasma to predicate device STA Deficient VIII		
Similarities		
Item	Submitted Device	Predicate Device
Intended use	NoFact VIII Deficient Plasma is a human plasma immunodepleted of Factor VIII and intended for the quantitative determination of Factor VIII activity in citrated plasma from patients suspected of FVIII deficiency. FVIII activity is based on the activated partial thromboplastin time. For in vitro diagnostic use.	STA Deficient VIII is an immunodepleted human plasma intended for use in tests for the determination of factor VIII activity in plasma by analyzers of the STA line suitable with this reagent.
Constituent material	Citrated human plasma immunodepleted of Factor VIII.	Citrated human plasma immunodepleted of Factor VIII.
Measurement principle	Diluted patient sample is mixed with factor VIII deficient plasma and then tested with an APTT. In these conditions the clotting time of the mixture is dependent on the concentration of FVIII in the patient sample.	Diluted patient sample is mixed with factor VIII deficient plasma and then tested with an APTT. In these conditions the clotting time of the mixture is dependent on the concentration of FVIII in the patient sample.
Format	Lyophilized plasma	Lyophilized plasma
Analyte being tested	Factor VIII activity	Factor VIII activity
Differences		
Item	Submitted Device	Predicate Device
Reconstituted Stability	2-8C: 8 hr RT: 4 hr	2-8C: not listed RT: not listed On-board STA Compact: 4 hrs

b. NoFact VIII Deficient Plasma was compared to the predicate STA FVIII Deficient plasma using the Stago PTT-A FVIII assay on the STA Compact. Plasma samples were assayed in parallel with the Stago PTT-A assay using the STA FVIII deficient plasma ("Stago results"), and also with the same assay but where the NoFact VIII deficient plasma was substituted for the STA FVIII deficient plasma ("NoFact results"). A total of two hundred thirty three frozen plasma samples in three

laboratories were analyzed. The linear regression equation of this comparison was: y = 0.8453x + 4.2111, with a coefficient of determination of 0.9683.

The regression statistics (with 95% confidence intervals for slope and intercept) by site were:

	All Labs n=233	Site 1 n=90	Site 2 n=90	Site 3 n=53
Slope	0.845 (0.825-0.865)	0.861 (0.844-0.878)	0.914 (0.891-0.936)	0.831 (0.777-0.884)
Intercept	4.2 (1.9-6.5)	2.8 (1.1-4.5)	2.5 (-0.1-5.1)	5.9 (-0.606-12.422)
R^2	0.968	0.991	0.986	0.953

c. The Stago PTT-A FVIII assay was evaluated for precision with three lots of NoFact VIII Deficient Plasma according to the CLSI guideline EP5-A2 "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-2nd Edition":

Plasma	Mean FVIII activity, %	% CV, Within-run (S-r)	% CV, Lot-to-Lot (S-lot)	% CV, Within-Device (S-device)
System N (Normal Control Plasma) n=240	91.6%	4.2%	0.63%	6.8%
System P (Abnormal Control Plasma) n=240	33.3%	4.9%	3.8%	8.0%
Low FVIII pooled patient plasma n=120	11.8%	5.7%	0.0%	8.5%

NoFact VIII Deficient Plasma provided acceptable precision.

NoFact VIII Deficient Plasma is substantially equivalent to Stago VIII Deficient Plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

r² Diagnostics, Inc.
c/o Mr. Marc D. Goldford
Director, Research and Development
1801 Commerce Drive.
South Bend, IN 46628

DEC 19 2011

Re: k102851
Trade/Device Name: NoFact VIII Deficient Plasma
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: Class II
Product Code: GJT
Dated: December 7, 2011
Received: December 8, 2011

Dear Mr. Goldford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Leena Philip

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102851

Device Name: NoFact VIII Deficient Plasma

Indications For Use: NoFact VIII Deficient Plasma is a human plasma immunodepleted of Factor VIII and intended for the quantitative determination of Factor VIII activity in citrated plasma from patients suspected of FVIII deficiency. FVIII activity is based on the activated partial thromboplastin time. For in vitro diagnostic use.

Prescription Use _X_____
(21 CFR Part 801 Subpart D)

And/Or Over the Counter Use_____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102851